ALLERGEN MIXING ASSISTANT

User Manual

XTRACT SOLUTIONS

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SM026R2

Welcome to Xtract Solutions

Thank you for purchasing the Allergen Mixing Assistant (AMA) from Xtract Solutions. Please review the instructions in this user manual **before** unpacking and set up. Should you have any questions or require support at any point, please call our customer support group at (503) 379-0110 ext. 2003 or email us at support@xtractsolutions.com.

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Product Disclaimer

The Allergen Mixing Assistant (AMA) and Syringe Keys are tools to assist mixing personnel with extract vial preparation. Proper use of these products is fully compatible with allergen immunotherapy extract preparation guidelines established by the Joint Council of Allergy, Asthma and Immunology.

Xtract Solutions does not make any recommendations related to source or type of extract, immunotherapy prescriptions, dosing schedules, dilution sets, labeling, expiration dates or any other standard operating procedures followed by mixing personnel in your clinic. We encourage you to continue to follow your clinic's guidelines unless otherwise directed by the physician or governing bodies.

Important Safety Instructions

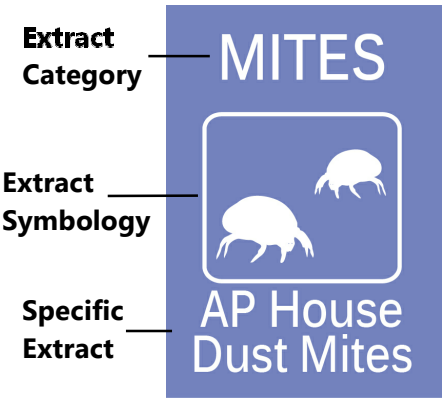
Your safety and the safety of others is very important. Please always read and obey all safety messages.
To reduce the risk of electric shock or injury when using your AMA, follow these basic precautions:

- Plug the power cord into a grounded 3-prong outlet, either in the wall or in an extension cord.
- Disconnect power before cleaning or maintenance.
- Use two or more people to move and install the AMA. Failure to do so can result in back or other injury.
- Install the AMA on a sturdy surface - countertop or medical cart - that can support at least 80 lbs.

The Syringe Keys included with your AMA are Class II medical devices cleared by the FDA to only be used as an accessory to the 1.0 mL Terumo SurSaver® and Optimix® syringes.

Do not use Syringe Keys with any other brand or type of syringe.

Main Components and Features



Exterior Label

Temperature Display Interface

1. Panel Button

Press this button to turn the refrigeration system on/off.

2. Status Indicator Ring

The status indicator ring glows various colors to indicate the system health and function.

- PULSING BLUE: Standby Mode
- BLUE: Nominal Function, Temperature Below 8°C
- YELLOW: Normal Function, Temperature Above 8°C
- RED: Normal Function, Temperature Above 8°C for more than 45 Minutes
- PULSING YELLOW: Empty Condensate Bottle Reminder
- PULSING PURPLE: Defrost Mode
- FLASHING RED: System Error, Contact Support

Accessories

Vial Adapters

Vial adapters may be needed if your clinic uses any small-top extract concentrate vials such as those found on some 10 mL vials.

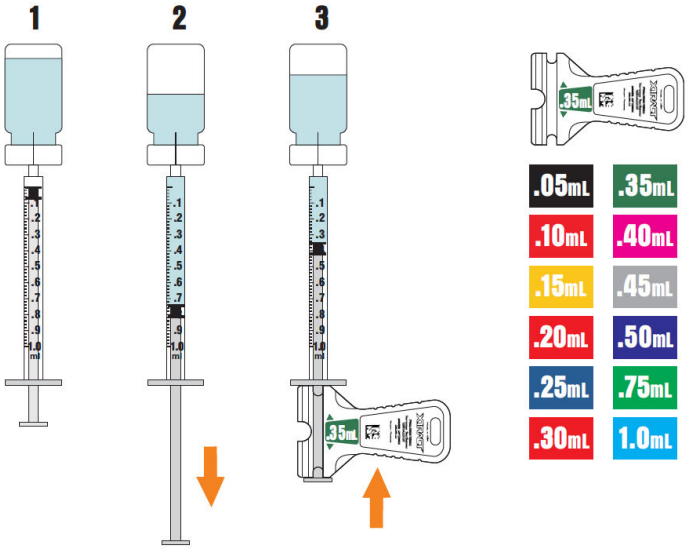
Snap the provided vial adapters onto the small-top vial to convert it to a standard-size vial before loading into the AMA.

Syringe Keys

Syringe Keys are hand-held tools designed to help the user to obtain rapid, accurate and precise volumetric draws from vials containing allergenic extracts.

While the Syringe Keys are not required to use the AMA, we strongly recommend incorporating them into your mixing routine for accurate, repeatable dosing.

Please see "Using Syringe Keys" on Page 7 for more information.



Unpacking & Setup

To remove the vial storage head from the box, set the box on its side. Slide the vial storage head out of the box using the handles and place it on the floor.

To remove the refrigeration base, grasp underneath the top of the black bearing plate and lift straight up out of the box and place it on the countertop or cart in your mixing area. The foam around the top of the refrigeration base is packed tightly into the box. We recommend another person holds the box down while you pull the base out of the box.

Remove the packaging materials from the cooling element on top of the refrigeration base and set aside. Remove the foam protecting the cooling element by pulling down on the colored tape. After removing the packaging materials, please inspect the equipment for concealed shipping damage. Please retain the packaging in the event you need to transport or store the AMA.

Once all packaging materials have been removed, lift the vial storage head using the handles and place it carefully on top of the refrigeration base. Rotate the head several times to ensure it spins freely. If the head does not spin freely, please check to make sure all the ball bearings (six) are snapped into place.

Please remember to complete and return your product acceptance form via fax to (503) 715-1378.

Water Bottle and Work Surface

If not already attached, connect the condensate water bottle to the nozzle on the back of your AMA by pushing in until you hear a "click."

To install the work surface, line up the thumb screws on the end of the prongs with the holes on the side of the refrigeration base. Pull the thumb screws out slightly and

Powering Up

1. Remove the power cord from the box and plug the lead into the back of the unit and the plug into a grounded 3-prong wall outlet or extension cord.
2. Turn on the master switch on the back of your AMA. Verify that top two green power-status indicators are illuminated.
3. After a brief self-test, the display window on the front of your AMA will now read **XTRACT SOLUTIONS AMA-CX**. Unit is now in Standby Mode.
4. Press the front-panel button to turn on the refrigeration unit and the display window will read **PRE-COOLING** and percentage to completion.

NOTE: Depending on shipping and environmental conditions it may take up to 2 hours for the internal temperature to stabilize within 2-8°C. It is recommended that you wait until the AMA's internal temperature has reached 2-8°C before loading the device with extract vials.

If the temperature has not fallen below 8°C after 2 hours, please contact Customer Support.

5. Once the unit has competed the Pre-Cooling routine it will begin to display the internal temperature. Once the temperature drops below 8°C it is safe to stock the unit with extracts.

Stocking Your AMA

Once the AMA has reached the 2-8°C temperature range, flip down all the refrigerator doors on your AMA. Wipe down the entire surface of the Vial Guide with 70% isopropyl alcohol and allow to dry prior to loading the extract vials. We recommend using cotton swabs or wipes instead of cotton balls.

Select the extract vials that correspond to the labels on the outside and inside of the doors, flip them over so the tops are facing down and snap the vial crimp into the notch on the Vial Guide. For your 10 mL vials, snap the Vial Adapters onto the cap, and then snap the whole assembly into the Vial Guides. Rotate the vials to ensure that the label is facing outwards.

CAUTION

Be sure to double-check that all the labels on the inside and outside of the refrigerator doors match

Once you have completely stocked your AMA with vials, close all the doors and allow several hours for the vials to cool down to 2-8°C.

Mixing a Patient Vial

1. Place the patient's formula in a visible location.

2. Place the patient's vial and mixing syringes on the counter or work surface.

3. Group the prescribed drugs by opening the doors of the extract vials listed in the patient's formula.

4. Wipe down all surfaces inside the vial storage door using 70% isopropyl alcohol and proper aseptic technique per pharmaceutical preparation guidelines.

5. Uncap a mixing syringe and slide it into the cylindrical channel on the Vial Guide until it pierces the rubber septum of the extract vial.

6. Repeat Step 5 for each extract vial in the formula.

7. Draw up the dose required for first prescribed extract. Use of the Syringe Keys is recommended.

8. Remove the syringe and dispense the dose into the patient vial.

9. Close the door of the dispensed extract to verify that it has been added.

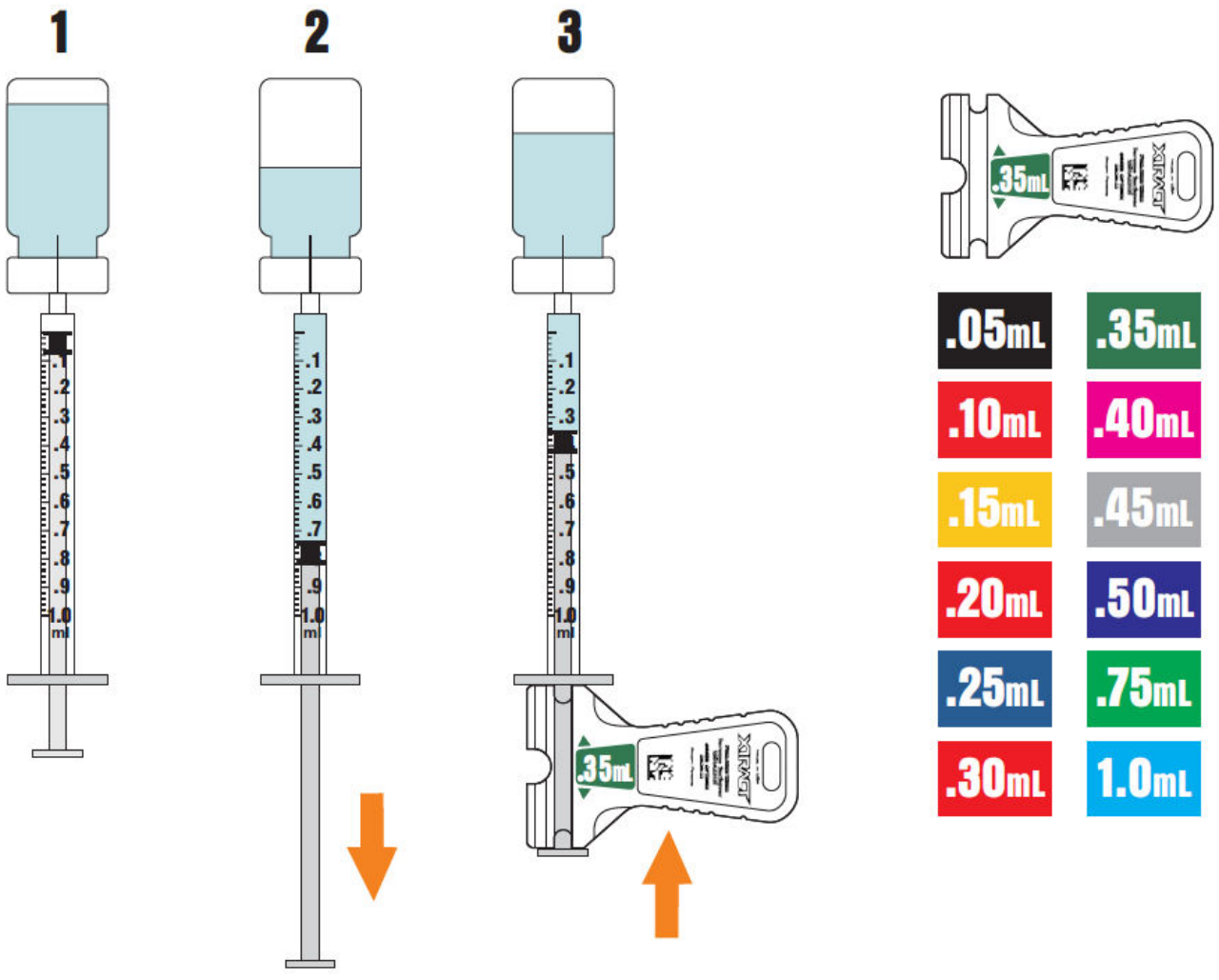
10. Repeat Steps 7-9 until all drugs have been added to the patient vial.

11. Mixing is now complete. Label and make dilution set as per your current clinic practices.

Using the Syringe Keys (For Use with Prescription Only)

NOTE: The Syringe Keys are not required to be used with the AMA. However, we strongly recommend using them to minimize dosing errors.

1. Please select the Syringe Key or Keys that correspond to the doses you plan to draw.
2. Place the Key or Keys, patient's vial and syringes on the counter or work surface.
3. Disinfect keys with 70% isopropyl alcohol prior to use.
4. Flip down the doors of the extract vials listed in the patient's formula.
5. Uncap a mixing syringe and slide it into the cylindrical channel on the Vial Guide until it pierces the rubber septum of the extract vial. **(Step 1)**
6. Repeat this step for each extract vial in the formula.
7. Draw the extract into the syringe barrel and then place the appropriate Syringe Key between the thumb rest on the end of the plunger and the finger flange. Brace the Vial Guide with your other hand as needed. You can use the edge on the end of the Key to draw out the plunger. (**Step 2)**
8. Press the thumb rest back until the Key limits further travel of the plunger. **(Step 3)**
9. You will now have the correct dose.
10. Remove the syringe and dispense the dose into the patient's vial.
11. Repeat these steps until the patient's formula is complete. Label the vial per your clinic's guidelines and place in the refrigerator.



Syringe Keys are Class II medical devices cleared by the FDA to only be used as an accessory to the 1.0 mL Terumo SurSaver® and Optimix® syringes.

DO NOT USE SYRINGE KEYS WITH ANY OTHER BRAND OR TYPE OF SYRINGE.

Powering Down

CAUTION

Always use the following procedures to power down your AMA. Do not push the Master Switch or unplug the AMA while it is running. Damage to the refrigeration system may result.

1. Only power-down the unit to move or clean.
2. Press the front-panel button once.
3. The display will read SHUTDOWN REQUEST, CLICK TO CONFIRM.
4. Press the front-panel button once again to initiate shut-down. The display will read SHUTDOWN OK, POWERING DOWN. A chime plays when shutdown.
5. The unit now in Stand-By Mode.
6. To fully power down your AMA, push the Master Switch in the back of the device.
7. You can now unplug the unit to move or clean.

Cleaning

CAUTION

Please do not attempt to clean the interior of the vial storage head while the AMA is powered on. This may result in electrocution or damage to the device.

1. Remove the rotating storage head on top of the AMA and place it on the counter and then remove the lid.
2. Use an anti-bacterial, all-purpose cleaner and a cloth or paper towels to wipe down all the surfaces on the inside of the rotating storage head.
3. Let the inside dry before placing the head back on the refrigeration unit.

Emptying the Water Bottle

1. Press the gray button to remove the connector and bottle from the nozzle on the AMA.
2. Unscrew the cap and pour the water into the sink.
3. Reattach the connector and push hard onto the nozzle into you hear a "click."

NOTE: Double-check to make sure the button on the connector is not depressed. If the bottle is not connected properly, water will pool inside the storage head and not drain properly.

Problems and Troubleshooting

If any of the following problems occur, please contact Customer Support at **(503) 379-0110 ext. 2003** or at s**upport@xtractsolutions.com** immediately:

- I have plugged in my AMA and flipped on the Master Switch in the back and the green lights have not come on.
- The green lights have come on but the display on the front of my AMA is blank.
- Display reads **SENSORS MISSING** or other error.
- Display reads **TEMP CRITICAL RESETTING.**

First try the solutions listed here before calling Customer Support.

Water is not draining properly inside the bottle storage head.

Your AMA may not be level on top of your counter or cart. Take the storage head off, tip the refrigeration base to the side and raise the feet on the left side by screwing them out 1-2 turns. Also check to make sure the condensate water bottle is fully attached to the nozzle in the

The storage head is not rotating properly.

Inspect the alignment to make sure it is not off-center. Also check to see if all the ball bearings are in the retainer

The temperature is out of the 2-8°C range.

If the AMA has been in use with the refrigerator doors down, temperature may go above 8°C. Please close all the refrigerator doors (if you have not done so already) and the temperature should return to 2-8°C. Also check to ensure the lid is on tightly and the bottle storage head is aligned and rotating correctly.

When the doors are flipped down, the vials are leaking.

This could be an effect of coring caused by repeatedly piercing the rubber septum in the same location. Due to variations between extract manufacturers, some brands of extracts are more prone to coring than others. The Vial Guides in which the vials are stored are designed with a slight offset so as to not pierce the septum dead-center.

Please rotate the vials within the Vial Guide periodically to ensure that you are piercing different parts of the septum's surface. We also recommend using a new syringe every time you enter the vial. Repeated use of the same syringe dulls the needle and could lead to excessive coring.